

Notice of Allowability

Application No.

09/804,980

Examiner

Rodney P. Swartz, Ph.D.

Applicant(s)

ANDERSEN ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12 July 2004.
2. ☒ The allowed claim(s) is/are 1-6, 9-11, 26, 28, 30 and 32.
3. ☒ The drawings filed on 13 March 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09289388.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 12July2004, is acknowledged.

Claims 2 and 4 have been amended.

2. Applicants' Terminal Disclaimer, received 12July2004, is acknowledged.
3. Claims 1-6, 9-11, 26, 28, 30, and 32 are pending and under consideration.

Rejections Withdrawn

4. The rejection of claims 1-6, 9-11, 26, 28, 30, and 32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 18-30 of U.S. Pat. No. 5,955,077 is withdrawn in light of the Terminal Disclaimer submitted.
5. The rejection of claims 4, 6, and 9-11 under 35 U.S.C. 112, second paragraph, as being indefinite for a "substantially pure" polypeptide and a fragment is "derived" from a virulent mycobacterium, is withdrawn in light of the claim amendments.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas J. Kowalski, Reg. No. 32,147, on 15September2004.

The application has been amended as follows:

Claims:

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28. (Currently Amended) ~~Vaccine according to claim 15 or 18, immunogenic~~
Immunogenic composition according to claim 10 or pharmaceutical composition according to
claim 26, characterized in that wherein said ~~vaccine/immunogenic composition~~
composition/pharmaceutical composition can be used prophylactically in a subject not infected
with a virulent mycobacterium; or therapeutically in a subject already infected with a virulent
mycobacterium.

Conclusion

6. Claims 1-6, 9-11, 26, 28, 30, and 32 are allowable.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

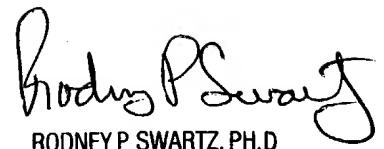
The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, reading "Rodney P. Swartz". The signature is written in a cursive style with a large, looped initial "R".

RODNEY P. SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 15, 2004